REMARKS/ARGUMENTS

This Amendment and Response comprises Applicant's Reply to the Examiner's non-final Office Action mailed on October 16, 2008. Claims 2, 3, 8, 9, 11, 14 and 19-21 are cancelled. Claims 1, 4-7, 10, 12-13, and 15-18 are currently amended. Claims 22-25 are new. Accordingly, Claims 1, 4-7, 10, 12-13, 15-18, and 22-25 are now pending in view of the above amendments. The Applicant believes that no new matter has been added with regard to the claim amendments and new claims provided herein. Applicant does not donate or disclaim any claims or subject matter with the claim amendments made herein, and the Applicant expressly reserves the right to prosecute the original claims or any unclaimed subject matter in one or more future filed continuing applications.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, the Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, is consistent with the Examiner's understanding. Also, Applicant's arguments related to each cited reference are not an admission that the cited references are, in fact, prior art.

I. Examiner's Interview

Applicant's Attorney expresses his sincere appreciation to the Examiner for conducting a telephone interview with Applicant's Attorney of record on January 20, 2009. An Interview Summary was prepared by the Examiner and mailed on January 23, 2009. Applicant's Attorney

is in agreement with the Examiner's Summary as set forth in the Interview Summary, including the claims and prior art discussed.

II. Rejection under 35 U.S.C. § 101

The Examiner rejected Claims 1, 3, 7, and 10-12 under 35 U.S.C. § 101 for being directed to non-statutory subject matter. In response, Claims 1, 4-7, 10, and 12 have been amended to include "for uniformly stabilizing" to overcome this rejection. Additionally, Claims 3 and 11 have been cancelled, thus, the rejection as to these claims is moot.

III. Rejection under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected Claims 5, 10, 11, 13, and 15-19 under 35 U.S.C. § 112, Second Paragraph for indefiniteness on the grounds that they did not distinctly claim the subject matter of the invention and possessed insufficient antecedent basis. In response, Claims 5, 10, 13, and 15-18 have been amended by specifically identifying specific discontinuous or continuous devices to overcome this rejection. Additionally, Claims 11 and 19 have been cancelled, thus the rejection to these claims is moot.

IV. PRIOR ART REJECTIONS

A. Rejections under 35 U.S.C. § 102(b) and § 102(e)

The Examiner rejected Claims 1, 3, 4, 7, 10, 12, 13, 17, and 18 under 35 U.S.C. § 102(b) as being anticipated by Ablaza (U.S. Patent No. 4,190,909). The Examiner states Ablaza discloses an apparatus comprising of an inner band stabilizer, outer band felt stabilizer, inner ring stabilizer, and outer ring felt stabilizer, of which the rings and bands are capable of proving the claimed function or placement and that the bands or rings are individual. The Examiner also states that Ablaza discloses the inner band/ring stabilizer is thinner than the surrounding area and that the inner band/ring and outer band/ring are a synthetic or biological material. Lastly, the

Examiner states Ablaza also teaches a method to implant a band inner stabilizer inside an aortic lumen, placing an outer band stabilizer outside the aortic lumen, implanting an STJ ring inner stabilizer inside the sinotubular junction, placing an STJ ring out stabilizer outside the sinotubular junction.

The Examiner also rejected Claims 1, 3, 4, 7, 10, 12, 13, 17, and 18 under 35 U.S.C. § 102(e) as being anticipated by Chevillon et al (U.S. Patent No. 6,511,506). The Examiner states Chevillon disclosed an apparatus comprising an inner band stabilizer, outer band felt stabilizer, inner band stabilizer, outer ring felt stabilizer, inner ring stabilizer, and outer ring felt stabilizer. The Examiner states rings/bands in Chevillon are individual and are capable of the placement of use claimed. The Examiner states Chevillon teaches a sewing passage that is thinner than a surrounding area. Additionally, the Examiner states Chevillon discloses three equally spaced markers on the circumference of the rings and that the bands/rings are made of synthetic or biological material.

As noted above, Claims 3 and 11 have been cancelled, thus, the rejections directed at these claims are moot.

It is well recognized that claims are anticipated if, and only if, each and every element, as set forth in the claim is found in a single prior art reference. Vertegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown as a complete detail as contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989). See MPEP § 2131. To constitute anticipation, all material elements of the claim must be found in one prior art source. In re Marshall, 198 U.S.P.Q. 344 (C.C.P.A. 1978). Additionally, the elements of the reference must be arranged as required by the claim. In re Bond, 15 U.S.P.Q. 2d 1566 (Fed. Cir. 1999). Applicant respectfully submits that the

cited reference does not teach all the materials elements and do not arrange the elements as required by the rejected claim language.

Claims 1 and 13, however, have been amended to now read, respectively:

1. An apparatus for restoring an aortic valve having an aortic annulus and a sinotubular junction, the apparatus comprising:
a) a discontinuous aortic annulus stabilizing device sized and configured to be implanted proximate the aortic annulus of the aortic valve for uniformly stabilizing a diameter of the aortic annulus; and
b) a continuous sinotubular junction stabilizing device sized and configured to be implanted proximate the sinotubular junction of the aortic valve for uniformly stabilizing a diameter of the sinotubular junction.

13. A treatment method for aortic valvular regurgitation comprising:
implanting a discontinuous aortic annulus stabilizing device proximate an aortic annulus of an aortic valve; and
implanting a continuous sinotubular junction stabilizing device proximate the sinotubular junction of the aortic valve.

Ablaza and Chevillon do not each teach each element of the claimed invention (e.g. the placement of a discontinuous aortic annulus stabilizing device sized and configured to be inserted proximate the aortic annulus of the aortic valve for uniformly stabilizing a diameter of the aortic annulus, nor the placement of a continuous sinotubular junction stabilizing device sized and configured to be inserted proximate the sinotubular junction of the aortic valve for uniformly stabilizing a diameter of the sinotubular junction.)

The apparatus disclosed in Ablaza has a flexible tube structure. In contrast, the present invention has discontinuous and continuous devices where the devices are used as one body. Further, the present invention is directed for use in an aortic annulus and a sinotubular junction; however, the apparatus disclosed in Ablaza is only used for arteries that have no valve. The apparatus disclosed in Ablaza is not suitable for the location where the present invention is to be

implanted. That is, the present invention is different from Ablaza with regard to the implant location.

With regard to Chevillon, this reference discloses an apparatus that has a tubular shape, and comprises complex components such as a tubular sleeve, frames, rings, strengtheners, etc. In contrast, the present invention has no tubular structure, and comprises components such as discontinuous and continuous devices. Lastly, as noted above in arguments in response to Ablaza, the present invention uses discontinuous and continuous devices where the devices are used as one body.

The present invention is used in an aortic annulus and a sinotubular junction, but the apparatus disclosed in Chevillon is only used in a blood vessel that has no valve. The apparatus disclosed in Chevillon is not suitable for the location where the present invention is to be implanted. In other words, the present invention is different from Chevillon in the aspect of implant location.

In short, since both Ablaza and Chevillon do not teach the apparatus and method as disclosed and claimed in this application. Applicant respectfully requests that the rejection of Claims 1, 3, 4, 5, 7, 10, 12, 13, 17, and 18 under 35 U.S.C. § 102(b) and 102(e) be withdrawn. Similarly, rejections to dependent Claims 12, 17, and 18 should be withdrawn as the independent Claims 1 and 13 with which they depend have been amended to overcome the Examiner's § 102 rejections.

In addition, notwithstanding the foregoing arguments and amendments above, because Chevillon is cited as a prior art reference under 35 U.S.C. § 102(e), Applicant does not admit that Chevillon is in fact prior art to the claimed invention, and, further, reserves his right to swear behind Chevillon, if necessary, to remove it as a reference.

B. Rejection Under 35 U.S.C. § 103

The Examiner rejected Claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Chevillon et al. as detailed above and further, the Examiner states that it would have been obvious to have margins of about 2 mm, and that it is not inventive to discover the optimum or workable ranges by routine experimentation. The Examiner also rejected Claim 16 under 35 U.S.C. § 103(a) as obvious over Chevillon in view of Ablaza as detailed above. The Examiner states if would have been obvious to combine Chevillon's method of inner and outer ring bands placed in aortic aneurysms, with Ablaza's teaching of particular placement at the sinotabular junction and aortic lumen. Claims 5, 11, 15, and 19 were also rejected by the Examiner under 35 U.S.C. § 103(a) as obvious over Ablaza in view of Tremulis (U.S. Patent Publication No. 2003/0069593 A1). The Examiner states Tremulis teaches the use of three equally spaced radiopaque markers on the ring implants in order to properly orient the implant and identification of attachment locations to the vessel. The Examiner states it would have been obvious to combine Ablaza's ring implants with Tremulis's teaching of placing three radioplaque markers on ring implants in order to properly orient and identify attachment locations for the ring to the vessel.

The U.S. Supreme Court, in KSR Int'l. Co. v. Teleflex Inc., 82 USPQ 2d 1385, 1391 (2007), reiterated the standard for determining obviousness under 35 U.S.C. § 103 as being the factual inquiries set forth in Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966). In Graham, the Court stated that obviousness is determined by first determining the scope and content of the prior art, then ascertaining the differences between the invention, as claimed, and the prior art, and then resolving the level of ordinary skill in the prior art. Against this background, the obviousness or non-obviousness of the claimed subject matter is determined.

Secondary considerations may also be utilized in this analysis to give light to the circumstances surrounding the origin of the subject matter sought to be patented. KSR Int'l Co., 82 USPQ 2d at 1391. When making any obviousness rejection, the Examiner must first acquire a thorough understanding of the claimed invention by reading the specification and claims to understand what the Applicant is claiming as his invention. See MPEP § 904.

To establish a prima facie case of obviousness under 35 U.S.C. §103(a), the Examiner must clearly articulate the reason(s) why the claimed invention would have been obvious (i.e., the analysis supporting the rejection must be made explicit.) See MPEP § 2142. "Rejections on obviousness cannot be sustained with mere conclusory statement; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." See MPEP § 2142; In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006); see also KSR Int'l Co., 82 USPQ 2d at 1396. To support a 103(a) rejection, the examiner must demonstrate that a person of ordinary skill in the art would have had reason to attempt to make the claimed device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so. See Noelle v. Lederman, 355 F.3d 1343, 1351–52 (Fed. Cir. 2004); Brown & Williamson Tobacco Co. v. Philip Morris, Inc., 229 F.3d 1120, 1121 (Fed. Cir. 2000); see also KSR Int'l Co., 82 USPQ2d at 1391.

Applicant traverses the Examiner's rejection for obviousness on the grounds that the references – either individually or in combination – fail to teach or suggest each and every element of the rejected claims. (See also Applicant's arguments above.) The present invention prevents aortic valve leaflets from hardening and being prolapsed through fixing the aortic annulus and the sinotubular junction with the devices of the present invention while allowing the aortic valves to function. Claim 6 of the present invention is a dependent claim to Claim 1. As

discussed above, Claim 1 of the present invention is different from Chevillon in the aspects of shape, components and applicable locations, and thus, it would not have been obvious to one having ordinary skill in the art at the time the invention was made to invent Claim 1 from Chevillon. Similarly, Claim 16 of the present invention is a dependent claim of Claim 13 comprising a discontinuous device aortic annulus repairing apparatus. Claim 16 of the present invention is used with an aortic annulus, however Ablaza and Chevillon are used for arteries (or blood vessels) that have no valve. The apparatuses disclosed in Ablaza and Chevillon are not suitable for the location where the present invention is to be implanted. Claim 16 of the present invention is different from Ablaza and Chevillon in the aspect of implant location, and it would not have been obvious to one having ordinary skill in the art at the time the invention was made to invent Claim 16 from the combination of Chevillon and Ablaza.

With regard to remaining dependent claims, namely, Claims 5, 11, 15, and 19, these claims are dependent claims of Claims 1 or 13. Thus, as discussed above, Claims 1 and 13 are different from Ablaza in the aspects of shape, components and implant location. As discussed in Tremulis, the use of three equally spaced radiopaque markers on the ring implants in order to properly orient the implant and identify attachment locations to the vessel is only a subsidiary measure. Accordingly, it would not have been obvious to one having ordinary skill in the art at the time the invention was made to invent the subject matter recited in Claims 5, 11, 15 and 19 from the combination of Ablaza and Tremulis.

V. New Claims

Applicant notes to Examiner's attention that Claims 22-25 are newly added. For the reasons set forth above, newly added Claims 22-25 are allowable because the underlying independent claims, Claims 1 and 13, are allowable. Further, Claims 22-25 do not recite any

limitation that is disclosed in the Examiner's cited references, namely, Ablaza, Chevillon and Tremulis.

CONCLUSION

In view of the foregoing, and consistent with the tentative agreement reached during the Examiner Interview, Applicant believes the claims as amended are in allowable form. In the event that the Examiner finds and remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Applicant also submits the requisite fee for a two-month extension of time. Please credit any overpayment or debit any under payment to Deposit Account No. 08-2665.

Respectfully submitted,

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